FEB 17 2012

510(k) Summary

Contact: Rosemary Harry
Vice President, Regulatory and Quality Affairs
Orthocon, Inc
1 Bridge Street, Suite 121
Irvington, NY 10533
harry@orthocon.com
914-357-2600

Date Prepared: January 18, 2012

Device Trade Name: Hemasorb® Resorbable Hemostatic Bone Putty

Manufacturer: Orthocon, Inc.
1 Bridge Street
Suite 121
Irvington, NY 10533

Common Name: Wax, bone

Classification: None applicable

Class: Unclassified

Product Code: MTJ

Indications For Use:
Hemasorb Resorbable Hemostatic Bone Putty is intended for use in the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade. The material may be used during surgical procedures and in treating traumatic injuries.

Device Description:
Orthocon Hemasorb Resorbable Hemostatic Bone Putty is a sterile, soft, moldable, biocompatible, absorbable material of putty-like consistency intended for use in the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade. The material is a mixture of calcium stearate, vitamin E acetate and a liquid surfactant. The material is virtually odorless, off-white in color and can be spread easily with minimal adhesion to surgical gloves. Hemasorb requires no kneading prior to application and does not soften appreciably at body temperature. The subject of this 510(k) is the addition of a spatula as an alternative method of Hemasorb application.

Predicate Devices:
Substantial equivalence was shown with the previously cleared devices in K043260 and K102762.

Summary of Non-Clinical Performance Testing
The *in vitro* tests performed were: simulated use and shipping (including mechanical tests of cyclic compression and tensile failure testing), finite element analysis, and stability (including sterile package integrity).

The device was determined to be biocompatible and to demonstrate adequate integrity and performance characteristics.

Conclusion:
The modification subject to this 510(k) was shown to be substantially equivalent to previously cleared devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 17 2012

Orthocon, Inc.
% Ms. Rosemary Harry
VP, RA/QA
1 Bridge Street, Suite 121
Irvington, New York 10533

Re: K113627
Trade/Device Name: Hemasorb® Resorbable Hemostatic Bone Putty
Regulatory Class: Unclassified
Product Code: MTJ
Dated: January 18, 2012
Received: January 20, 2012

Dear Ms. Harry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113627

4. Indications for Use

510(k) Number (if known): K113627

Device Name: Hemasorb® Resorbable Hemostatic Bone Putty

Hemasorb Resorbable Hemostatic Bone Putty is intended for use in the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade. The material may be used during surgical procedures and in treating traumatic injuries.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Kraus for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113627